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| APPLICATION NO.              | FILING DATE | FIRST NAMED INVENTOR       | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------------|---------------------|------------------|
| 09/529,210                   | 07/24/2000  | GORDON REX PATERSON DOUGAL | 9052-53             | 1793             |
| 20792                        | 7590        | 10/08/2003                 | EXAMINER            |                  |
| MYERS BIGEL SIBLEY & SAJOVEC |             |                            | JOHNSON, HENRY I    |                  |
| PO BOX 37428                 |             |                            |                     |                  |
| RALEIGH, NC 27627            |             |                            | ART UNIT            | PAPER NUMBER     |
|                              |             |                            | 3739                | 29               |
| DATE MAILED: 10/08/2003      |             |                            |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

N.R.

|                              |                 |                                |
|------------------------------|-----------------|--------------------------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)                   |
|                              | 09/529,210      | DOUGAL, GORDON REX<br>PATERSON |
| Examiner                     | Art Unit        |                                |
| Henry M Johnson, III         | 3739            |                                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 29 July 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1 and 5-26 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1 and 5-26 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .      6) Other: \_\_\_\_\_

**DETAILED ACTION**

The finality of the previous Office action is hereby withdrawn due to additional defects in the application as cited below. Applicant's amendment submission after final filed on 7/29/2003 has been entered.

The rejections of the previous office action No. 22, mailed on July 28, 2003 are maintained.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim1 is rejected under 35 U.S.C. 112, first paragraph, because it is a single means claim (MPEP § 2164.08(a)). A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph.

***Response to Arguments***

Applicant's arguments filed May 30, 2002 have been fully considered but they are not persuasive. The treatment of a specific condition (e.g. herpes) is an intended use. No claim includes treatment of a specific condition. The wavelengths cited by Salansky in claim 1, include the specific wavelengths of 1072 nm and 1268 nm of the instant application. The bandwidth cited by Salansky is not to exceed 30-40 nm. The narrow band as claimed in the amended claim 1 of the application, while not specifically defined in the specification, is defined in the paper written by the applicant (supplied by applicant with the amendment) as a bandwidth

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of  $\pm$  20 nm. Thus Salansky clearly anticipates the bandwidth of the application. Salansky teaches power densities at the high end from 1 to 5 W/cm<sup>2</sup> over a range of wavelengths from 400 to 2000 nm (Col. 4, lines 21-22. This anticipates the at least 50 microwatts/ cm<sup>2</sup> and the 2 W/cm<sup>2</sup> of the application.

The fact that Salansky does not recognize the surprising effects of any particular wavelength is considered moot to an apparatus claim with no stated intended use. While the declaration provides further data, such data is not persuasive in an apparatus claim. The data from the declaration would have stronger impact on a 35 USC § 103 rejection or when addressing method claims.

Likewise, the arguments regarding LED's are not applicable, as claim 1 of Salansky cites no LED in the claim. The use of LED's in the application with a bandwidth of 120 nm as cited in the amendment is contradictory to the applicant's article, "A Pilot of Treatment of Herpes Labialis with 1072 nm Narrow Waveband Light" which discloses the narrow band to be  $\pm$  20 nm.

The argument regarding narrow ranges within broad ranges is likewise not persuasive. In re Woodruff (CA FC) 16 USPQ2d 1934, as referenced in the amendment, addresses an appeal of 35 USC § 103 rejections of method claims. This is very different than 35 USC § 102 rejections of apparatus claims, although the rejections were affirmed. There is no basis for criticality of ranges for apparatus only claims.

#### ***Claim Rejections - 35 USC § 102***

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being

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examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6-12, and 15-24 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,063,108 to Salansky et al. Salansky et al discloses an apparatus for treating tissue that uses radiation in the range of 400-2000nm (Col. 3, line 44) with an intensity of from 0.2 to 5000 mW/cm<sup>2</sup>. The apparatus uses light emitting diodes (Col. 3, line 51) that inherently produce divergent radiation. Diodes, by definition, include a PN junction. Salansky et al teaches the radiation can be either pulsed or continuous with average powers adjustable by the processor over a wide range by varying the pulse repetition rates over a wide range of hertz and the pulse durations from microsecond to milliseconds (Col 14, line 31). The treatments disclosed by Salansky et al, provide exposure times from 3 to 500 seconds (Table 8) and dosages in Joules/ cm<sup>2</sup> (Table 5) as is common in the art. A display shows system parameters such as timer, power, and frequency (Col. 23, line 24). Salansky et al teaches treating numerous afflictions including herpes (Col. 37, line 17). The treatments indicated in claims 7-9 are intended use and have been given limited patentable weight. Figure 13 shows a flexible applicator that can be wrapped around the surface contours of the body (Col. 26, line 1) that inherently reduces the amount of ambient light.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,063,108 to Salansky et al. Salansky et al does not disclose expressly the specific divergence of the emitting device. Applicant has not disclosed that the increased beam divergence provides any advantage or unexpected result. Therefore, pending a statement of criticality, the cited divergence is considered to be an obvious design choice to one having ordinary skill in the art.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,063,108 to Salansky et al. Salansky et al cites repetition frequencies from 0 to 200 Hz and 1000 to 10,000 Hz, yet does not disclose 201 to 999 Hz specifically. Applicant has not disclosed that the specific repetition rate provides any advantage or unexpected result. Salansky et al teaches treatment routines for many different afflictions that are programmed as protocols into the processor that controls the frequency, pulse width and repetition rate. There is no evidence that use of the unique frequency/repetition rate would produce any unexpected results. Therefore, pending a statement of criticality, the cited frequency/repetition rate is considered to be an obvious design choice to one having ordinary skill in the art.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,063,108 to Salansky et al in view of U.S. Patent 5,527,350 to Grove et al. Salansky et al is discussed above. Grove discloses the use of gas lasers (Col. 1, line 56) in tissue treatment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a gas laser as disclosed by Grove et al in the device of Salansky et al to obtain the wavelength desired for treatment.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,063,108 to Salansky et al in view of Lasers and Electro-Optics by Christopher C. Davis, Cambridge University Press 1996, page 289. Salansky et al does not specifically disclose a

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diode with multiple PN junctions. The use of multiple PN junctions is old and well known in the art of LED construction as disclosed by Lasers and Electro-Optics by Christopher C. Davis, thereby making their use an obvious design choice.

### ***Conclusion***

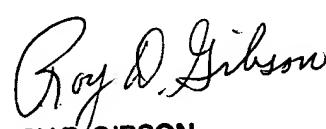
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (703) 305-0910. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Henry M Johnson, III  
Patent Examiner  
Art Unit 3739

Hmj

  
ROY D. GIBSON  
PRIMARY EXAMINER